

*REMARKS/ARGUMENTS**Claim Amendments*

Claims 1-9, 14 and 19-21 are pending. The pending claims have been amended to clarify the subject matter recited therein and/or to avoid unnecessary language. New claim 19 has been added to define the amorphous solid as a flowing powder, and new claims 20 and 21 have been added to recite lactose and donepezil hydrochloride as the inactive and active ingredients, respectively, in certain ratios. Support for the amendments and new claim can be found in the specification, e.g., at paragraphs [0014] - [0016] and [0020]. Claims 10-13 and 15-18 have been canceled as being directed to non-elected subject matter. Applicants reserve the right to pursue the non-elected subject matter in one or more continuing/divisional applications.

*Anticipation Rejection*

Claims 1-9 and 14 have been rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Weisman (U.S. Patent No. 6,734,195). Applicants respectfully traverse. Weisman does not disclose a stable, amorphous solid that includes an amorphous active pharmaceutical ingredient and at least one amorphous pharmaceutically acceptable inactive ingredient as recited in the instant claims. To the contrary, the mixtures produced according to Weisman are essentially crystalline. For example, Weisman (col. 2, lines 17-25) states:

Testing the tablets by X-ray diffraction in order to evaluate the crystalline properties of the active material is not a simple task. Most of the donepezil tablet is inactive ingredients. Being crystalline compounds they do have X-ray diffraction pattern. This pattern has to be subtracted from the total pattern in order to see the peaks that originate from donepezil hydrochloride. The fact that donepezil hydrochloride itself is only a small part of the formulation makes it even harder.

Thus, the mixtures of Weisman had such a high degree of crystallinity that it was difficult to determine whether amorphous donepezil hydrochloride was even present in the composition. By contrast, the composition of the present invention is essentially amorphous, and exhibits remarkable morphological stability. For instance, the composition of the present

invention showed no evidence of crystallinity generated after 2 months storage at 40° C and 75% relative humidity, after 20 minutes at 120° C, and even after being compressed at a force of 10 tons for one minute. See the instant specification, e.g., at paragraphs [0037] - [0039]. No such composition is disclosed by Weisman. Further, Weisman does not disclose the ratios of inactive to active ingredients recited in the instant claims, and the Office has admitted that Weisman fails to disclose such ratios (Office Action, p. 4). Applicants therefore submit that Weisman does not anticipate the claimed invention. In view of the foregoing, withdrawal of the anticipation rejection is respectfully solicited.

#### *Obviousness Rejection*

Claims 1-9 and 14 have been rejected under 35 U.S.C. § 103(a) as allegedly obvious over Weisman in view of Straub (US 2002/0142050). Applicants respectfully traverse. Subject matter that qualifies as prior art only under one or more of 35 U.S.C. §§ 102(e), 102(f) and 102(g) shall not preclude patentability under 35 U.S.C. § 103 where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person. 35 U.S.C. § 103(c)(1). In the instant case, the subject matter of Weisman (cited as prior art under 35 U.S.C. § 102(e)) and the claimed invention were owned by the same person or subject to an obligation of assignment to the same person at the time the claimed invention was made. Accordingly, Applicants submit that Weisman should be disqualified as prior art for obviousness purposes in the instant case.

Straub describes porous drug matrices that contain a drug, which may be crystalline or amorphous, and one or more excipients. According to Straub, the excipient may serve as an “anti-crystallization agent” for drugs in an amorphous state or a “crystal growth inhibitor” for drugs in a crystalline state. Straub, however, does not provide any guidance as to which of the literally hundreds of drugs disclosed therein is amorphous and which is crystalline. For instance, Straub does not teach or suggest any particular morphology associated with “donepezil” (mentioned in claim 10 and paragraph [0073]), or whether the donepezil is in the form of a free base or a salt. Further, Straub is completely silent as to the morphology of the literally hundreds of excipients disclosed therein. As such, Straub does not teach or suggest a stable, amorphous solid mixture that includes an amorphous active pharmaceutical ingredient and at least one amorphous pharmaceutically acceptable inactive ingredient as recited in the

instant claims. Accordingly, Applicants submit that the claimed invention is not obvious over the cited art. In view of the foregoing, withdrawal of the obviousness rejection is respectfully solicited.

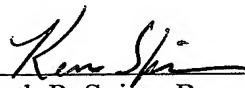
#### *Double Patenting Rejection*

Claims 1, 2 and 14 have been rejected on the ground of obviousness-type double patenting over claims 1-4 of U.S. Patent No. 6,734,195 (Weisman). Applicants respectfully traverse. Claims 1-3 of Weisman recite compositions that contain amorphous donepezil hydrochloride, and claim 4 of Weisman recites amorphous donepezil hydrochloride *per se*. Claims 1-4 of Weisman are silent as to any carriers or inactive ingredients, and do not disclose or suggest combining an amorphous active ingredient with an amorphous inactive ingredient as recited in claims 1, 2 and 14 of the present application. Accordingly, Applicants submit that the inventions recited in claims 1, 2 and 14 of the present application are not obvious variations of the subject matter recited claims 1-4 of Weisman. In view of the foregoing, withdrawal of the obviousness-type double patenting rejection is respectfully solicited.

#### *Conclusion*

Applicants respectfully submit that the subject application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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